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In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

The Controlled Substances Act (CSA) bans the unauthorized distribution of marijuana for all purposes, including purported medical uses, 21 U.S.C. 841(a)(1), and authorizes courts to enjoin violations of the Act. 21 U.S.C. 882. Respondents nonetheless ask this Court to hold that they may not be enjoined from distributing marijuana for medical purposes, even though marijuana is a schedule I controlled substance and has never been approved by the Food and Drug Administration (FDA) as safe and effective to treat any medical condition. To justify that result, respondents argue that the CSA does not clearly preclude a common law defense of "medical necessity" (Br. 17-22), that in any event a court has equitable power to decline to enjoin the illegal distribution of marijuana for medical purposes (Br. 11-17), and, finally, that if the CSA does not contain a defense of medical necessity then it is unconstitutional (Br. 27-50). Each of those arguments lacks merit.

1. *The Act forecloses a common law "medical necessity" defense*

a. Respondents argue (Br. 17-21, 29) that a common law defense of "medical necessity" is no more precluded by the CSA than a common law defense of entrapment or duress. But this argument ignores the fact that the common law defense of necessity by its own terms exists only where the legislature has not manifested a contrary intent. Here, the CSA clearly manifests the intent to prohibit the illegal distribution of marijuana for claimed medical purposes.

Respondents urge (Br. 16) the Court to look beyond the text of the CSA to "our broader notions of justice and common sense," and contend on this basis (Br. 21-22, 24-25) that, while the CSA generally bars the unauthorized distribution or use of marijuana, Congress did not intend to bar such conduct when a jury determines in a particular case that

marijuana is medically efficacious and that lawful drugs are ineffective at treating a user's pain and suffering.

But banning marijuana in those circumstances is precisely what Congress did do in the CSA, by imposing criminal sanctions for the distribution of controlled substances—*drugs*—that otherwise could be put to medical use. See 21 U.S.C. 321(g)(1) ("The term 'drug' means * * * articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man."); 21 U.S.C. 802(6) (the term "controlled substances" means a scheduled "drug"); 21 U.S.C. 802(12) (incorporating 21 U.S.C. 321(g)(1)). Since its enactment in 1970, the CSA has made it a crime to "manufacture, distribute, or dispense" marijuana, "[e]xcept as authorized by" the Act itself (21 U.S.C. 841(a)(1))—*i.e.*, unless the person handling the marijuana is registered with the DEA to conduct research approved by the FDA (21 U.S.C. 355(i) and 823(f)), or the Attorney General, after consultation with the Secretary of Health and Human Services (HHS), determines under 21 U.S.C. 811 that marijuana no longer meets the statutory criteria for a schedule I controlled substance of having "no currently accepted medical use in treatment in the United States," "a high potential for abuse," and "a lack of accepted safety for use * * * under medical supervision," 21 U.S.C. 812(b)(1).

Consistent with that plain text, the CSA's structure and purposes conclusively demonstrate that Congress did not intend to permit juries to excuse the illegal distribution of marijuana based on a claimed need to avert medical harm. As explained in our opening brief (at 20-23), the CSA imposes stringent and uniform controls on the handling of all controlled substances, even those drugs that are listed in schedules II through V because there is a "currently accepted medical use" for the drugs and thus doctors may prescribe them to patients, 21 U.S.C. 812(b)(2)-(5). *A fortiori*, Congress did not intend to permit a schedule I drug, which has no currently accepted medical use, to be distri-

buted for medical purposes outside the strict confines of the Act itself.

A "medical necessity" defense would be utterly inconsistent with the provisions of the CSA requiring handlers to comply with DEA registration, production quotas, reporting, record-keeping, and order-form requirements, and, for schedules II through V drugs, prescription requirements. 21 U.S.C. 821-829. Contrary to respondents' characterization of those controls as requiring the "bureaucratic completion of a paper trail for every transfer of a pill" (Br. 24), those controls are essential to effectuate Congress's intent to create a closed system of drug distribution to combat the dangers of drug abuse and diversion. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 3, 6 (1970); see also *United States* v. *Moore*, 423 U.S. 122, 135, 141 (1975); U.S. Br. 6, 21-22.[1]

This Court also should take no comfort in respondents' representation (Br. 9, 17-19) that they intend to distribute marijuana to only a "minuscule" number of persons who face "death, blindness, or starvation." The Ninth Circuit's decision invites district courts to permit the illegal distribution of marijuana to *any* person who has a "serious medical condition[]" and whose physician "certifies[]" that legal drugs "are ineffective" or "result in intolerable side effects." App. 7a, 39a.[2] The court's decision places no limit on the number of people to whom respondents may distribute marijuana or the quantity of marijuana that they may distribute, either in the aggregate or to particular customers. Even if

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[1] By contrast, respondents' self-imposed "protocols," which bar smoking on their premises and require members to receive identification cards, undergo screening interviews, and provide a verifiable doctor's note assenting to marijuana "therapy," App. 3a-4a & n.4, bear no resemblance to the CSA's comprehensive and unified set of controls.

[2] The express terms of the district court's orders do not even require a doctor's certification of medical necessity. See App. 33a-35a.

the recognition of a "medical necessity" defense could be confined to the distribution of marijuana (and no other schedule I drugs)—and there is no basis to conclude that it could—the court's decision seriously undermines the effectiveness and administration of the Act.

As we also explain in our opening brief (at 23-25), a "medical necessity" defense is directly contrary to the CSA's exclusive rescheduling provisions, 21 U.S.C. 811, 812, which give the Attorney General, after consultation with the Secretary of HHS, the authority to determine whether marijuana has an accepted medical use. Those rescheduling provisions authorize judicial review of any final decision by the Attorney General declining to reschedule a controlled substance, 21 U.S.C. 877, but in the absence of a rescheduling decision, they leave no room for district courts or juries to determine on a case-by-case basis whether marijuana may be used as medicine.

Finally, any question regarding congressional intent is put to rest by the statutory provision enacted by Congress in 1998 entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE." Act of Oct. 21, 1998, Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761. That provision reiterates that drugs are placed in schedule I precisely because they "lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision"; that marijuana has not been approved by the FDA "to treat any disease or condition"; and that Congress "opposes efforts to circumvent" the drug approval process "by legalizing marijuana * * * for medicinal use without valid scientific evidence and the approval of the [FDA]." *Ibid.* Those statutory recitations confirm Congress's determination not only that marijuana lacks any accepted medical utility, but also that marijuana may not be used to treat any medical

condition unless and until the FDA finds that marijuana is safe and effective.[3]

Respondents attempt to diminish the force of the 1998 legislation by arguing (Br. 34) that neither court below "purported to 'legalize' marijuana." Judicial authorization to distribute marijuana where the Act does not allow it, however, *does* "legaliz[e] marijuana * * * for medicinal use." 112 Stat. 2681-761. Respondents also observe (Br. 35) that the 1998 statute "makes no mention of necessity." But as we explain in our opening brief (at 17-19), a necessity defense is foreclosed when its application would fatally clash with the criminal statute's language, structure, or purpose. The CSA prohibits the unauthorized distribution of marijuana for all purposes, and the 1998 legislation confirms that prohibition with respect to the use of marijuana for asserted medical purposes.[4]

b. Respondents argue (Br. 23-24) that by placing marijuana in schedule I, and defining the criteria for schedule I to include no currently accepted medical use," 21 U.S.C. 812(b)(1), Congress did not itself determine that marijuana has "no currently accepted medical use," but merely limited the Attorney General's authority to change its classification. That argument defies logic. By placing marijuana in schedule I, Congress banned the unauthorized distribution of marijuana for all purposes, unless and until the Attorney General affirmatively determines that marijuana no longer meets schedule I's criteria of having "no currently accepted

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[3] A "medical necessity" defense also cannot be reconciled with the statutory and regulatory schemes under the CSA and the FDCA that reject the medical use of illegal drugs based on patients' and physicians' subjective views or anecdotal accounts, "no matter how fervently held," that the drug is safe and effective. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973); see U.S. Br. 31-34.

[4] For similar reasons, respondents err in relying (Br. 27-28) on the rule of lenity, which has no application unless this Court "can make no more than a guess as to what Congress intended." *Holloway* v. *United States*, 526 U.S. 1, 12 n.14 (1999) (internal quotation marks omitted).

medical use in treatment in the United States," "a high potential for abuse," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1).[5] It would have made no sense for Congress to authorize the Attorney General to remove marijuana from schedule I in the event he determines that the drug no longer meets those criteria, unless Congress had made the initial judgment that it did meet the criteria. See 21 U.S.C. 812(c) (listing schedule I drugs "unless and until amended" by the Attorney General under 21 U.S.C. 811); see also 116 Cong. Rec. 1664 (1970) (statement of Sen. Hruska) ("Marijuana is included in schedule I since it comes squarely within the criteria of that schedule.").

c. Respondents further argue (Br. 28-31) that the CSA countenances some medical use of marijuana because HHS continues to supply eight individuals with marijuana for medical use pursuant to single-patient investigational new drug (IND) exemptions under 21 U.S.C. 355(i) and 823(f).[6]

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[5] For example, as respondents and their amici observe (Resp. Br. 23 n.19; Sheriff Dion *et al.* Br. 11), Congress has directed the Attorney General to place in schedule I methaqualone and gamma-hydroxybutyrate that is not contained in a drug product approved by the FDA, so that those drugs would be subject to the CSA's most stringent controls and banned for all purposes, including medical uses. Hillory J. Farias & Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7; Act of June 29, 1984, Pub. L. No. 98-329, 98 Stat. 280. Those directives demonstrate that Congress would not want a jury, acting pursuant to a common law "medical necessity" defense, to override its judgment regarding the medical use of those drugs.

[6] Under single-patient IND exceptions, the FDA permits a doctor to give an unapproved, investigational drug to a single patient. The FDA's primary objectives in reviewing an IND are to assure the safety and rights of subjects and to help assure the quality of the scientific evaluation of the drug's safety and effectiveness. See 21 C.F.R. 312.22. In the case of a single-patient IND, the patient is not part of a controlled clinical trial intended to determine whether the drug is safe and/or effective. We have been informed by the FDA that, for that reason, single-patient INDs do not provide much information that assists the agency in determining whether the drug is safe or effective.

That contention, however, confuses the limited and controlled distribution of marijuana by the *federal government* pursuant to *statute* with the illegal and unregulated distribution of marijuana by private parties. Those limited IND exemptions thus are fully consistent with Congress's intent to ban the distribution of marijuana for all purposes, including purported medical uses, except as controlled under the Act. In any event, HHS's single-patient INDs do not support the medical use of marijuana. In 1992, HHS ceased granting the INDs because the "widespread use of marijuana for medical purposes * * * is bad public policy and bad medical practice." *Kuromiya* v. *United States*, 78 F. Supp. 2d 367, 369 (E.D. Pa. 1999). Moreover, the government "never conceded formally that marijuana was effective in treating the symptoms of those individuals who were receiving it," *id.* at 369, and "consistently expressed skepticism about [the single-patient INDs] and the efficacy of using marijuana." *Id.* at 372.

d. Respondents purport (Br. 32-34) to find support for a *federal* "medical necessity" defense in the fact that some States have enacted statutes that carve out an exception to blanket statutory prohibitions similar to those in the CSA in order to authorize limited medical uses of marijuana. But because Congress did not enact such a statute, the cited state provisions point in precisely the opposite direction, demonstrating that when legislatures want to provide exceptions for some medical use of marijuana they know how to do so. Therefore, the absence of any exception in the CSA for medical use, coupled with Congress's steadfast adherence to the placement of marijuana in schedule I and its 1998 rejection of a "medicinal" use exception (112 Stat. 1281-761), clearly reflects Congress's intent to foreclose a common law necessity defense that would circumvent the CSA's strict prohibitions and controls.

2. *Courts lack the equitable power to permit the illegal distribution of marijuana based on a claimed medical need*

Respondents and their amici argue that this Court need not decide whether "medical necessity" is a valid legal defense under the Act, because the court of appeals' decision may be upheld on the ground that a district court has the equitable discretion under 21 U.S.C. 882 to refuse to enforce the CSA if the court determines that the balance of the equities favors the availability of marijuana for medical purposes. A district court undoubtedly has discretion to fashion an injunction under the CSA in the manner best suited to terminate violations of and secure compliance with the Act. U.S. Br. 37-43. But a federal court's equity power does not allow it to countenance ongoing violations of the CSA by refusing to enjoin the distribution of marijuana for medical purposes on the ground that there is a public interest in such use, in the face of Congress's contrary balancing of the relevant scientific, medical, and public policy considerations.[7]

a. As we explain in our opening brief (Br. 37-43), this Court's precedents confirm that when the United States brings an action for an injunction to enforce an Act of Congress, the court must exercise its equitable discretion in light of the text, structure, and underlying policies of the

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[7] Not even the court of appeals held that a district court may "ignore the law" in light of its view of the public interest. App. 8a. Rather, the court held that the district court abused its discretion in enjoining respondents' distribution of marijuana for all purposes, including medical uses, because the court failed "to take into account a legally cognizable defense" under the CSA. *Ibid.*; see also *id.* at 9a (explaining that, by seeking an injunction, "the government invited an inquiry into whether the injunction" should be "broad enough to prohibit *illegal* conduct, but narrow enough to exclude conduct that likely would be *legally privileged or justified*") (emphasis added); *ibid.* (finding that modification of the injunction would not conflict with the CSA's underlying policies); *id.* at 11a (remanding for district court to consider whether respondents met "the criteria for a medical necessity exemption").

statute that the court is charged with enforcing. Thus, *United States* v. *Rutherford*, 442 U.S. 544 (1979), held that a district court lacked the power to enter an injunction permitting the physician-supervised use of Laetrile by terminally ill cancer patients, because the FDCA "makes no special provision for drugs used to treat terminally ill patients." *Id.* at 551; U.S. Br. 27-28, 39. The CSA likewise "makes no special provision" for the unauthorized distribution of marijuana for medical purposes, regardless of whether a court sitting in equity is of the view that such distribution is "medically necessary." Congress already has determined that the unauthorized distribution of controlled substances, including marijuana, has "a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C. 801(2), and therefore has banned their unauthorized use. A court thus cannot defeat those policy judgments based on its own view that they are unwise or unfair. *Rutherford*, 442 U.S. at 551, 555, 559.[8]

b. Respondents also argue (Br. 12, 16) that a court may refuse to enjoin violations of the CSA when the government makes the "tactical" choice to forgo a criminal prosecution. In their view (Br. 16), a court may "require" the government to enforce the CSA solely by bringing a criminal prosecution, in which, they assert, a jury could take a "dim view of the governmental attempt to deprive grievously ill citizens of medication essential for relief during the last days of their lives."

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[8] Respondents attempt (Br. 35-37) to distinguish *Rutherford* on the ground that "[t]here was no credible evidence * * * that Laetrile was a cancer cure," whereas marijuana is the only drug of "proven effectiveness" for their members' conditions. *Rutherford* cannot credibly be read, however, as turning on the plaintiffs' inability to "prove" to a *court* that Laetrile was medically advantageous. Rather, *Rutherford* held that Congress had banned the use of Laetrile absent a finding by the *FDA* that the drug was safe and effective, as required by the FDCA. 442 U.S. at 551-559. Congress likewise has banned the medical use of marijuana absent FDA approval and rescheduling by the Attorney General.

The Act authorizes the Attorney General and not a court, however, to decide whether to enforce the Act through criminal or civil proceedings. A district court has no authority to refuse to enjoin flagrant and ongoing violations of the Act on the ground that the court believes the government should have proceeded criminally instead. It would defeat Congress's decision to authorize enforcement through civil injunctive relief if a court could decline to enforce the Act on the ground that the government did not seek the more onerous form of relief.[9]

Respondents' contention fails for another reason. Although a jury may have the *de facto* power to render a criminal verdict of acquittal "in the teeth of both law and facts," *Horning* v. *District of Columbia*, 254 U.S. 135, 138 (1920), a court has no authority to instruct a jury that it has that power, see, *e.g.*, *United States* v. *Edwards*, 101 F.3d 17, 19-20 (2d Cir. 1996) (collecting cases), or to exercise it itself. A court likewise has no discretion to refrain from enjoining ongoing violations of the Act on the ground that a jury might find the violations sympathetic and therefore nullify the Act.

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[9] For similar reasons, amici ACLU *et al.* err in contending (Br. 21-27) that a court should refrain from enjoining violations of the CSA because, although the CSA provides for a trial by jury in instances of an alleged violation of a civil injunction, see 21 U.S.C. 882(b), contempt proceedings lack some of the procedural safeguards of a criminal trial. Amici ACLU *et al.* also contend (Br. 14 n.7) that the district court's orders on remand leave the government "a viable alternative" of pursuing a criminal prosecution against respondents. That alternative hardly seems "viable" in light of the Ninth Circuit's recognition of a "medical necessity" defense and the district court's orders that permit respondents to violate the Act.

3. *The CSA's ban on marijuana distribution for medical purposes satisfies constitutional requirements*

Respondents and their amici argue that the CSA should not be construed to foreclose a "medical necessity" defense in order to avoid what they assert is a difficult constitutional question. As respondents recognize (Br. 37), however, that canon of construction has no application absent statutory ambiguity. *Whitman* v. *American Trucking Ass'ns*, 121 S. Ct. 903 (2001). As we explain above and in our opening brief, Congress spoke with unmistakable clarity in precluding the illegal distribution of marijuana despite a claimed "medical necessity." Moreover, all of the constitutional challenges, to the extent they are properly before this Court, lack merit.[10]

a. Respondents argue (Br. 37-41) that Congress lacks the power under the Commerce Clause, Art. I, § 8, Cl. 3, to ban the intrastate distribution of marijuana for medical purposes. That is not correct.[11] Congress's commerce authority

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[10] The court of appeals did not address respondents' constitutional claims, and respondents did not raise the Commerce Clause challenge in the court of appeals. Moreover, respondents did not mention the Ninth and Tenth Amendments in their brief opposing certiorari, although they stated in a footnote in their brief opposing the government's motion to stay the district court's remand orders that the court of appeals' decision could be supported on Ninth and Tenth Amendment grounds. Stay Opp. 10 n.2. Finally, as we note in our certiorari petition (at 5 n.5), respondents' substantive due process claim is currently before the district court on remand from the Ninth Circuit.

[11] Every court of appeals has upheld the constitutionality of the CSA under the Commerce Clause. *United States* v. *Edwards*, 98 F.3d 1364, 1369 (D.C. Cir. 1996), cert. denied, 520 U.S. 1170 (1997); *United States* v. *Lerebours*, 87 F.3d 582, 584-585 (1st Cir. 1996), cert. denied, 519 U.S. 1060 (1997); *United States* v. *Genao*, 79 F.3d 1333, 1336-1337 (2d Cir. 1996); *United States* v. *Orozco*, 98 F.3d 105, 107 (3d Cir. 1996); *United States* v. *Leshuk*, 65 F.3d 1105, 1112 (4th Cir. 1995); *United States* v. *Clark*, 67 F.3d 1154, 1165-1166 (5th Cir. 1995), cert. denied, 517 U.S. 1141 (1996); *United States* v. *Tucker*, 90 F.3d 1135, 1140-1141 (6th Cir. 1996); *United States* v. *Westbrook*, 125 F.3d 996, 1009-1010 (7th Cir.), cert. denied, 522 U.S. 1036 (1997); *United States* v. *Brown*, 72 F.3d 96, 97 (8th Cir. 1995) (per curiam),

includes the power to regulate intrastate economic activity that substantially affects interstate commerce. *United States* v. *Morrison*, 529 U.S. 598, 611-612 (2000); *United States* v. *Lopez*, 514 U.S. 549, 559-560 (1995)).[12] Marijuana distribution is economic activity. See, *e.g.*, *United States* v. *Orozco*, 98 F.3d 105, 107 (3d Cir. 1996) ("drug trafficking is an inherently commercial activity"); *United States* v. *Rogers*, 89 F.3d 1326, 1338 (7th Cir.) ("drug dealing is an economic activity"), cert. denied, 519 U.S. 999 (1996). Marijuana is a tradable commodity for which there exists a substantial and national market. 21 U.S.C. 801(3) ("A major portion of the traffic in controlled substances flows through interstate and foreign commerce."). Indeed, respondents do not dispute that they *sell* marijuana to their members. See J.A. 50 ("marijuana for sale * * * ranged in price from between $28 to $85 per one-eighth ounce"), J.A. 60 (20 grams of "Afghani Hash" sold for $400); see also J.A. 64-65, 72.[13]

Respondents therefore err in arguing (Br. 39-41) that the CSA cannot constitutionally be applied to their intrastate drug distribution for medical purposes because the government has not shown that particular activity to substantially affect interstate commerce. "[W]here a general regulatory statute bears a substantial relation to commerce, the de

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cert. denied, 518 U.S. 1033 (1996); *United States* v. *Tisor*, 96 F.3d 370, 373-375 (9th Cir. 1996), cert. denied, 519 U.S. 1140 (1997); *United States* v. *Wacker*, 72 F.3d 1453, 1475 (10th Cir. 1995), cert. denied, 523 U.S. 1035 (1998); *United States* v. *Jackson*, 111 F.3d 101, 102 (11th Cir.), cert. denied, 522 U.S. 878 (1997).

[12] The activities regulated by the statutes at issue in *Morrison* and *Lopez* were found to be non-economic in nature. *Morrison*, 529 U.S. at 617 (gender-motivated violence covered by Violence Against Women Act of 1994, 42 U.S.C. 13981); *Lopez*, 514 U.S. at 551, 561, 567 (gun possession in a local school zone banned by Gun-Free School Zones Act of 1990, 18 U.S.C. 922(q)(1)(A)).

[13] Respondents' alleged non-profit character (Br. 2; J.A. 29) does not exempt them from Congress's Commerce Clause authority. See *Camps Newfound/Owatonna, Inc.* v. *Town of Harrison*, 520 U.S. 564, 583-586 (1997).

minimis character of individual instances arising under that statute is of no consequence." *Lopez*, 514 U.S. at 558 (emphasis and internal quotation marks omitted); see also *Perez* v. *United States*, 402 U.S. 146, 154 (1971); *Maryland* v. *Wirtz*, 392 U.S. 183, 192 (1968); *United States* v. *Darby*, 312 U.S. 100, 120-121 (1941). For example, in *Wickard* v. *Filburn*, 317 U.S. 111 (1942), the Court upheld federal regulation of wheat grown and consumed on a family farm in order to control the volume of wheat moving in interstate and foreign commerce. See *Lopez*, 514 U.S. at 559-561; *Morrison*, 529 U.S. at 610-611.

Respondents argue (Br. 41 n.35) that *Wickard* is inapposite because, unlike the wheat at issue in *Wickard*, "there is no federal scheme of price maintenance" for marijuana affected by respondents' intrastate activities. The intrastate distribution of marijuana for medical purposes, however, substantially affects the interstate market for marijuana by increasing the drug's demand and supply, and by interfering with the CSA's purpose to establish a national and uniform closed system to prevent the abuse and diversion of illegal drugs. See 21 U.S.C. 801(4) (finding that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances."); 21 U.S.C. 801(6) (finding that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic").[14] As the district court explained in rejecting

[14] Congress in the CSA also found that "[i]ncidents of the [drug] traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a *substantial and direct effect upon interstate commerce* because – (A) after manufacture, many controlled substances are transported in interstate commerce, (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession." 21 U.S.C. 801(3) (emphasis added).

respondents' Commerce Clause challenge, "[m]edical marijuana may be grown locally, or out of the state or country, and there is nothing in the nature of medical marijuana that limits it to intrastate cultivation. Similarly, it may be transported across state lines and consumed across state lines. * * * [Marijuana] distribution [is] a class of activities that, even if done for the humanitarian purpose of serving the legitimate health care needs of seriously ill patients, can affect interstate commerce." App. 59a.

b. Nor is there any merit to the suggestion of respondents and their amici (see, *e.g.*, Resp. Br. 45-49) that banning respondents' distribution of marijuana would violate the Tenth Amendment because Proposition 215 reflects the State of California's determination that marijuana has medical utility.

This Court "long ago rejected the suggestion that Congress invades areas reserved to the States by the Tenth Amendment simply because it exercises its authority under the Commerce Clause in a manner that displaces the States' exercise of their police powers" or that "curtail[s] or prohibit[s] the States' prerogatives to make legislative choices respecting subjects the States may consider important." *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 290, 291 (1981). Thus, in the absence of federal "commandeer[ing of] the state legislative process by requiring a state legislature to enact a particular kind of law," *Reno* v. *Condon*, 528 U.S. 141, 149 (2000), the Tenth Amendment "states but a truism that all is retained which has not been surrendered," *Darby*, 312 U.S. at 124. "If a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States," *New York* v. *United States*, 505 U.S. 144, 156 (1992). Because the CSA's generally applicable prohibition against manufacture, distribution, and possession of marijuana is a valid exercise of Congress' Commerce Clause authority, pp. 11-13, *supra*, that prohibition does not

violate the Tenth Amendment. See, *e.g.*, *Reno*, 528 U.S. at 149-150 (rejecting Commerce Clause and Tenth Amendment challenges to federal statute imposing civil and criminal penalties upon state and private actors for improper disclosure of certain state motor vehicle records); see also *United States* v. *Westbrook*, 125 F.3d 996, 1010 (7th Cir.) (rejecting Tenth Amendment challenge to CSA), cert. denied, 522 U.S. 1036 (1997); accord *United States* v. *Lerebours*, 87 F.3d 582, 585 (1st Cir. 1996), cert. denied, 519 U.S. 1060 (1997); *United States* v. *Owens*, 996 F.2d 59, 60-61 (5th Cir. 1993).

Moreover, nothing in Proposition 215 purports either to override federal law or to legalize the distribution of marijuana for medical purposes.[15] Rather, Proposition 215 exempts from the State's own criminal laws the possession and cultivation of marijuana for medical use by a "patient[] or [the] patient's primary care-giver * * * upon the oral or written recommendation or approval of a physician." Cal. Health & Safety Code § 11362.5(d) (West 2001). Proposition 215 therefore does not authorize respondents' conduct.[16] Indeed, the State itself has successfully closed "medical-marijuana" distribution clubs because they violate California's laws that *criminalize* the selling, furnishing, or giving

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[15] Because there is no occasion in this case to determine whether Proposition 215 conflicts with the CSA, respondents' reliance (Br. 9) on 21 U.S.C. 903, which provides that the CSA shall not be construed to displace state law absent "positive conflict" with state law, is inapposite.

[16] For that reason, respondents err in suggesting (Br. 16) that the district court could exercise its discretion to decline "to restrain state officers in the administration of state law." In any event, even if we assume, arguendo, that respondents are "state officers" because the City of Oakland has designated them to administer the City's marijuana distribution "Program," J.A. 146, respondents would not be permitted to distribute marijuana in violation of federal law. *Condon*, 528 U.S. at 149-150; cf. 21 U.S.C. 885(d) (providing immunity under CSA for state officials "engaged in the enforcement" of controlled substances laws).

away of marijuana. *People* v. *Peron*, 70 Cal. Rptr. 2d 20, 25-28 (1997), review denied (Feb. 25, 1998).[17]

c. Respondents and their amici further argue (see, *e.g.*, Resp. Br. 42-49) that individuals have a Ninth Amendment and substantive due process right to use marijuana when doctors and their patients conclude that such use is "medically necessary." Respondents and their amici have not established, however, that the use of a *particular* drug (much less the receipt of the drug from a distributor), free of a regulatory regime designed to protect the public health and safety, is a fundamental right that is deeply rooted in "our Nation's history, legal traditions, and practices." *Washington* v. *Glucksberg*, 521 U.S. 702, 710 (1997); cf. *Employment Div., Dep't of Human Res. of Or.* v. *Smith*, 494 U.S. 872 (1990) (rejecting claim of Free Exercise right to religiously motivated peyote use).[18]

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[17] Respondents err in asserting (Br. 1 n.2) that marijuana distribution is not authorized by Proposition 215 because one of its purposes is to "*encourage* the federal and state governments to implement a *plan* to provide for the safe and affordable distribution of marijuana to all patients in medical need." Cal. Health & Safety Code § 11362.5(b)(1)(C) (West 2001) (emphases added); see also *Peron*, 70 Cal. Rptr. 2d at 28 (rejecting contention that Section 11362.5(b)(1)(C) indicates an intent to authorize the distribution of small amounts of marijuana for medical purposes, explaining that the "drafters [of Proposition 215] were aware of both state and federal law prohibiting such sales and were attempting to avoid a conflict therewith"). Equally irrelevant is respondents' observation (Br. 1 n.2) that the district court "assumed" that state law applied to respondents' conduct in order "to avoid a factual dispute." App. 47a.

[18] The lower courts repeatedly have held that governmental regulations designed to protect health and safety do not infringe a fundamental right merely because they restrict a patient's choice of a particular medical treatment. See, *e.g.*, *Mitchell* v. *Clayton*, 995 F.2d 772, 775-776 (7th Cir. 1993) ("[a] patient does not have a constitutional right to obtain a particular type of treatment * * * if the government has reasonably prohibited that type of treatment"); *Carnohan* v. *United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (per curiam) ("[c]onstitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power"); *Rutherford* v. *United States*, 616 F.2d 455, 457 (10th Cir.) (a patient's "selection of a particular

Such a right would be inconsistent with this country's history of restrictions on the distribution and use of medicinal and "street" drugs. As early as 1736, Virginia began to regulate the practice of pharmacy, and by the time of the Civil War, four States had similar laws. Pharmaceutical regulation intensified in the period after the Civil War, such that by 1900, with the exception of Nevada, every State had passed laws regulating the practice of pharmacy, and at least 25 States or territories had passed laws prohibiting drug adulteration and regulating the sale of poisons. 37 David L. Cowen, *Pharmacy in History: The Development of State Pharmaceutical Law* 49-50 (1995).

In 1906, Congress passed the Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, to prohibit the manufacture of adulterated or misbranded food or drugs. In 1914, Congress passed the predecessor to the CSA, the Harrison Narcotics Act, ch. 1, 38 Stat. 785, which restricted the use of narcotics such as opium, morphine, and cocaine in order to combat the problems of abuse and addiction. Cf. *Moore*, 423 U.S. at 132 (noting that "[p]hysicians who stepped outside the bounds of professional practice could be prosecuted under the [Harrison Act]."). In 1938, Congress passed the FDCA, which requires FDA approval of drugs in order to "protect the public health by ensuring that . . . drugs are safe and effective." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) (quoting 21 U.S.C. 393(b)(2) (1994 & Supp. III 1997)); accord *United States* v. *Walsh*, 331 U.S. 432, 434 (1947).

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treatment, or at least a medication, is within the area of governmental interest in protecting public health"), cert. denied, 449 U.S. 937 (1980); *Kuromiya* v. *United States*, 37 F. Supp. 2d 717, 726 (E.D. Pa. 1999) (rejecting constitutional challenge to CSA by individuals seeking to use marijuana for medical purposes, concluding that "there is no fundamental right of privacy to select one's medical treatment without regard to criminal laws"); see also U.S. Br. 25 n.14.

After marijuana use in this country first became popular among limited segments of the population in the mid-1920s, the National Conference of Commissioners on Uniform State Laws in 1932 recommended passage of the Uniform Narcotic Drug Act, which included an optional provision to list marijuana as a narcotic subject to strict controls. By 1937, every State, either by adoption of the Uniform Act or by separate legislation, had restricted or prohibited marijuana use. R.J. Bonnie & C.H. Whitebread, *The Marihuana Conviction* 31-52, 79-91 (1974); National Comm'n on Marihuana & Drug Abuse, *Marihuana: A Signal Of Misunderstanding* 13-14, 104-105 (Mar. 1972). Also in 1937, Congress passed the Marihuana Tax Act, ch. 553, 50 Stat. 551, which severely restricted the use of and trafficking in marijuana, even for medical purposes. *United States* v. *Sanchez*, 340 U.S. 42, 43-44 (1950); see also R.J. Bonnie & C.H. Whitebread, *supra*, at 165. That long-standing tradition of governmental regulation to protect the public from unsafe or improperly diverted drugs (including marijuana) cannot be reconciled with the assertion of a fundamental right to use a particular drug (including marijuana) free of governmental regulation to protect the public health and safety.

There is also no basis for concluding that Congress has infringed on the liberty interests of individuals who seek to relieve their pain and suffering. The CSA does not deprive citizens of the ability to obtain medication to treat disease or relieve pain and suffering. Rather, the CSA outlaws the unauthorized use of a particular unapproved drug, marijuana, based on judgments made by Congress, the Secretary of Health and Human Services, and the Attorney General that marijuana has no currently accepted medical use, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Congress, the Secretary, and the Attorney General made that determination in furtherance of their obvious and compelling interest in combating drug abuse and protecting the public from the dangers associated

with the use of unsafe drugs that may be diverted for improper purposes. See *National Treasury Employees Union* v. *Von Raab*, 489 U.S. 656, 668, 674 (1989) (observing that drug trafficking is "one of the greatest problems affecting the health and welfare of our population" and that "drug abuse is one of the most serious problems confronting our society today"); see also *Smith*, 494 U.S. at 905 (O'Connor, J., concurring) (State has a "compelling" and "overriding interest in preventing the physical harm caused by the use of a Schedule I controlled substance").

Congress, moreover, has ensured that government restrictions on controlled substances are well-founded. The CSA authorizes research with respect to possible medical uses of marijuana, albeit under the strict confines of the Act. See 21 U.S.C. 823(f); see also 21 U.S.C. 355(i). The CSA permits the Attorney General to reschedule marijuana if he determines that marijuana no longer meets the criteria of a schedule I drug, including that it has "no currently accepted medical use." 21 U.S.C. 811, 812(b)(1)(B). The FDCA similarly authorizes the FDA to approve marijuana for medical use if it finds that marijuana is safe and effective for any intended medical use. 21 U.S.C. 355. Congress also has authorized courts to review final agency action under those Acts and to overturn those that are arbitrary or capricious or not supported by substantial evidence. 21 U.S.C. 355(h), 877.[19]

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[19] Although respondents and their amici express their belief in the therapeutic benefits of marijuana and their frustration with the potentially time-consuming process of rescheduling marijuana or obtaining FDA approval of the drug, they have not petitioned the DEA to reschedule marijuana based on a claim that it has a "currently accepted medical use," see U.S. Br. 24 & n.12, and they do not assert that they have requested the FDA to approve marijuana as safe and effective for any medical condition.

As we noted in our opening brief (at 24 n.12), on July 10, 1995, Jon Gettman petitioned the DEA to initiate rulemaking proceedings to reschedule marijuana on the asserted ground that marijuana lacks a high

Finally, there is nothing inherently suspect about Congress's medical and policy judgments regarding marijuana. All citizens have an interest in obtaining medication that is "proven" to treat disease or to relieve the pain and suffering of those who are sick or terminally ill. Therefore, "[t]here is no reason to think the democratic process will not strike the proper balance" between the interest of those individuals and Congress's interest in ensuring that drugs are safe and effective and are not used or diverted for improper purposes. *Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring); cf. *City of Cleburne* v. *Cleburne Living Ctr., Inc.*, 473 U.S. 432, 445 (1985).

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For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

BARBARA D. UNDERWOOD
Acting Solicitor General

MARCH 2001

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potential for abuse. By letter dated March 20, 2001, the Administrator of DEA notified Mr. Gettman that his petition was denied, explaining that both the DEA and HHS have concluded that marijuana continues to meet the criteria for placement in schedule I of having a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use even under medical supervision. We are lodging with the Court the DEA's response to Mr. Gettman's petition, which also contains the scientific and medical recommendation that HHS's Assistant Secretary for Health and Surgeon General provided to the Administrator on January 17, 2001.